

State Board of Health

12 VAC 5-220

**Virginia Medical Care Facilities Certificate of Public Need
Rules and Regulations**



Center for Quality Health Care Services and Consumer Protection
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VIRGINIA DEPARTMENT OF HEALTH
VIRGINIA MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED
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CHAPTER 220.
VIRGINIA MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED
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Part I.
Definitions.

12 VAC 5-220-10. Definitions.

The following words and terms, when used in these regulations, shall have the following meanings, unless the context clearly indicates otherwise:

"Acquisition" means an expenditure of \$600,000 or more that changes the ownership of a medical care facility. It shall also include the donation or lease of a medical care facility. An acquisition of a medical care facility shall not include a capital expenditure involving the purchase of stock. See 12 VAC 5-220-120.

"Amendment" means any modification to an application that is made following the public hearing and prior to the issuance of a certificate and includes those factors that constitute a significant change as defined in this chapter. An amendment shall not include a modification to an application that serves to reduce the scope of a project.

"Applicant" means the owner of an existing medical care facility or the sponsor of a proposed medical care facility project submitting an application for a certificate of public need.

"Application" means a prescribed format for the presentation of data and information deemed necessary by the board to determine a public need for a medical care facility project.

"Application fees" means fees required for a project application and application for a significant change. Fees shall not exceed the lesser of 1.0% of the proposed capital expenditure or cost increase for the project or \$20,000.

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"Board" means the State Board of Health.

"Capital expenditure" means any expenditure by or in behalf of a medical care facility that, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance. Such expenditure shall also include a series of related expenditures during a 12-month period or a financial obligation or a series of related financial obligations made during a 12-month period by or in behalf of a medical care facility. Capital expenditures need not be made by a medical care facility so long as they are made in behalf of a medical care facility by any person. See definition of "person."

"Certificate of public need" means a document that legally authorizes a medical care facility project as defined herein and which is issued by the commissioner to the owner of such project.

"Clinical health service" means a single diagnostic, therapeutic, rehabilitative, preventive or palliative procedure or a series of such procedures that may be separately identified for billing and accounting purposes.

"Commissioner" means the State Health Commissioner who has authority to make a determination respecting the issuance or revocation of a certificate.

"Competing applications" means applications for the same or similar services and facilities that are proposed for the same planning district or medical service area and which are in the same review cycle. See 12 VAC 5-220-220.

"Completion" means conclusion of construction activities necessary for substantial performance of the contract.

"Construction" means the building of a new medical facility or the expansion, remodeling, or alteration of an existing medical care facility.

"Construction, initiation of" means that a project shall be considered under construction for the purpose of certificate extension determinations upon the presentation of evidence by the owner of: (i) a signed construction contract; (ii) the completion of short term financing and a commitment for long term (permanent) financing when applicable; (iii) the completion of predevelopment site work; and (iv) the completion of building foundations.

"Date of issuance" means the date of the commissioner's decision awarding a certificate of public need.

"Department" means the Virginia Department of Health.

"Designated medically underserved areas" means (i) areas designated as medically underserved

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areas pursuant to § 32.1-122.5 of the Code of Virginia; (ii) federally designated Medically Underserved Areas (MUA); or (iii) federally designated Health Professional Shortage Areas (HPSA).

"Ex parte" means any meeting that takes place between (i) any person acting in behalf of the applicant or holder of a certificate of public need or any person opposed to the issuance or in favor of the revocation of a certificate of public need and (ii) any person who has authority in the department to make a decision respecting the issuance or revocation of a certificate of public need for which the department has not provided 10 days written notification to opposing parties of the time and place of such meeting. An ex parte contact shall not include a meeting between the persons identified in (i) and staff of the department.

"Gamma knife surgery" means stereotactic radiosurgery, where stereotactic radiosurgery is the noninvasive therapeutic procedure performed by directing radiant energy beams from any source at a treatment target in the head to produce tissue destruction. See definition of "project."

"Health planning region" means a contiguous geographical area of the Commonwealth with a population base of at least 500,000 persons that is characterized by the availability of multiple levels of medical care services, reasonable travel time for tertiary care, and congruence with planning districts.

"Informal fact-finding conference" means a conference held pursuant to §§2.2-4019 of the Code of Virginia.

"Inpatient beds" means accommodations within a medical care facility with continuous support services (such as food, laundry, housekeeping) and staff to provide health or health-related services to patients who generally remain in the medical care facility in excess of 24 hours. Such accommodations are known by varying nomenclatures including but not limited to: nursing beds, intensive care beds, minimal or self care beds, isolation beds, hospice beds, observation beds equipped and staffed for overnight use, and obstetric, medical, surgical, psychiatric, substance abuse, medical rehabilitation and pediatric beds, including pediatric bassinets and incubators. Bassinets and incubators in a maternity department and beds located in labor or birthing rooms, recovery rooms, emergency rooms, preparation or anesthesia inductor rooms, diagnostic or treatment procedures rooms, or on-call staff rooms are excluded from this definition.

"Medical care facility" means any institution, place, building, or agency, at a single site, whether or not licensed or required to be licensed by the board or the State Mental Health, Mental Retardation and Substance Abuse Services Board, whether operated for profit or nonprofit and whether privately owned or operated or owned or operated by a local governmental unit, (i) by or in which facilities are maintained, furnished, conducted, operated, or offered for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition, whether medical or surgical, of two or more non-related mentally or physically sick or injured persons, or

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for the care of two or more non-related persons requiring or receiving medical, surgical, or nursing attention or services as acute, chronic, convalescent, aged, physically disabled, or crippled or (ii) which is the recipient of reimbursements from third party health insurance programs or prepaid medical service plans. For purposes of this chapter, only the following medical care facility classifications shall be subject to review:

1. General hospitals.
2. Sanitariums.
3. Nursing homes.
4. Intermediate care facilities, except those intermediate care facilities established for the mentally retarded that have no more than 12 beds and are in an area identified as in need of residential services for people with mental retardation in any plan of the Department of Mental Health, Mental Retardation and Substance Abuse Services.
5. Extended care facilities.
6. Mental hospitals.
7. Mental retardation facilities.
8. Psychiatric hospitals and intermediate care facilities established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts.
9. Specialized centers or clinics or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, radiation therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, or such other specialty services as may be designated by the Board by regulation.
10. Rehabilitation hospitals.
11. Any facility licensed as a hospital.

For purposes of this chapter, the following medical care facility classifications shall not be subject to review:

1. Any facility of the Department of Mental Health, Mental Retardation and Substance Abuse Services.
2. Any nonhospital substance abuse residential treatment program operated by or contracted primarily for the use of a community services board under the Department of Mental Health, Mental Retardation and Substance Abuse Services Comprehensive Plan.
3. Any intermediate care facility for the mentally retarded that has no more than 12 beds and is in an area identified as in need of residential services for people with mental retardation in any plan of the Department of Mental Health, Mental Retardation and Substance Abuse Services
4. Any physician's office, except that portion of the physician's office which is

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- described in subdivision 9 of the definition of "medical care facility" excluding that portion dedicated to providing nuclear cardiac imaging.
5. The Woodrow Wilson Rehabilitation Center of the Virginia Department of Rehabilitative Services.

"Medical service area" means the geographic territory from which at least 75% of patients come or are expected to come to existing or proposed medical care facilities, the delineation of which is based on such factors as population characteristics, natural geographic boundaries, and transportation and trade patterns, and all parts of which are reasonably accessible to existing or proposed medical care facilities.

"Modernization" means the alteration, repair, remodeling, replacement or renovation of an existing medical care facility or any part thereto, including that which is incident to the initial and subsequent installation of equipment in a medical care facility. See definition of "construction."

"Operating expenditure" means any expenditure by or in behalf of a medical care facility that, under generally accepted accounting principles, is properly chargeable as an expense of operation and maintenance and is not a capital expenditure.

"Operator" means any person having designated responsibility and legal authority from the owner to administer and manage a medical care facility. See definition of "owner."

"Other plans" means any plan(s) which is formally adopted by an official state agency or regional health planning agency and which provides for the orderly planning and development of medical care facilities and services and which is not otherwise defined in this chapter.

"Owner" means any person who has legal responsibility and authority to construct, renovate or equip or otherwise control a medical care facility as defined herein.

"Person" means an individual, corporation, partnership, association or any other legal entity, whether governmental or private. Such person may also include the following:

1. The applicant for a certificate of public need;
2. The regional health planning agency for the health planning region in which the proposed project is to be located;
3. Any resident of the geographic area served or to be served by the applicant;
4. Any person who regularly uses health care facilities within the geographic area served or to be served by the applicant;
5. Any facility or health maintenance organization (HMO) established under § 38.2-4300 et seq. of the Code of Virginia that is located in the health planning region in which the project is proposed and that provides services similar to the services of the medical care facility project under review;

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6. Third party payors who provide health care insurance or prepaid coverage to 5.0% or more patients in the health planning region in which the project is proposed to be located; and
7. Any agency that reviews or establishes rates for health care facilities.

"Physician's office" means a place, owned or operated by a licensed physician or group of physicians practicing in any legal form whatsoever, which is designed and equipped solely for the provision of fundamental medical care whether diagnostic, therapeutic, rehabilitative, preventive or palliative to ambulatory patients and which does not participate in cost-based or facility reimbursement from third party health insurance programs or prepaid medical service plans excluding pharmaceuticals and other supplies administered in the office. See definition of "medical care facility."

"Planning district" means a contiguous area within the boundaries established by the Department of Housing and Community Development as set forth in § 15.2-4202 of the Code of Virginia, except that for purposes of this chapter, Planning District 23 shall be divided into two planning districts; Planning District 20 consisting of the counties of Isle of Wight and Southampton and cities of Chesapeake, Franklin, Norfolk, Portsmouth, Suffolk and Virginia Beach; and Planning District 21 consisting of the counties of James City and York and the cities of Hampton, Newport News, Poquoson and Williamsburg.

"Predevelopment site work" means any preliminary activity directed towards preparation of the site prior to the completion of the building foundations. This includes, but is not limited to, soil testing, clearing, grading, extension of utilities and power lines to the site.

"Primary medical care services" means first-contact, whole-person medical and health services delivered by broadly trained, generalist physicians, nurses and other professionals, intended to include, without limitation, obstetrics/gynecology, family practice, internal medicine and pediatrics.

"Progress" means actions that are required in a given period of time to complete a project for which a certificate of public need has been issued. See 12 VAC 5-220-450, Demonstration of Progress.

"Project" means

1. The establishment of a medical care facility. See definition of "medical care facility."
2. An increase in the total number of beds or operating rooms in an existing or authorized medical care facility.
3. Relocation at the same site of 10 beds or 10% of the beds, whichever is less, from one existing physical facility to another in any two-year period; however, a hospital shall not be required to obtain a certificate for the use of 10% of its beds

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- as nursing home beds as provided in § 32.1-132 of the Code of Virginia.
4. The introduction into any existing medical care facility of any new nursing home service such as intermediate care facility services, extended care facility services or skilled nursing facility services except when such medical care facility is an existing nursing home as defined in § 32.1-123 of the Code of Virginia.
 5. The introduction into an existing medical care facility of any new cardiac catheterization, computed tomography (CT), gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), medical rehabilitation, neonatal special care services, obstetrical services, open heart surgery, positron emission tomographic (PET) scanning, organ or tissue transplant service, radiation therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, psychiatric, substance abuse treatment, or such other specialty clinical services as may be designated by the board by regulation, which the facility has never provided or has not provided in the previous 12 months.
 6. The conversion of beds in an existing medical care facility to medical rehabilitation beds or psychiatric beds.
 7. The addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization, computed tomography (CT), gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, or other specialized service designated by the board by regulation.
 8. Any capital expenditure of \$5 million or more, not defined as reviewable in subdivisions 1 through 7 of this definition, by or in behalf of a medical care facility. However, capital expenditures between \$1 million and \$5 million shall be registered with the commissioner.

"Public hearing" means a proceeding conducted by a regional health planning agency at which an applicant for a certificate of public need and members of the public may present oral or written testimony in support of or opposition to the application that is the subject of the proceeding and for which a verbatim record is made. See subsection A of 12 VAC 5-220-230.

"Regional health plan" means the regional plan adopted by the regional health planning agency board.

"Regional health planning agency" means the regional agency, including the regional health planning board, its staff and any component thereof, that performs health planning activities within a health planning region.

"Rural" means territory, population, and housing units that are classified as "rural" by the Bureau of the Census of the United States Department of Commerce, Economics and Statistics Administration.

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"Schedule for completion" means the timetable that identifies the major activities required to complete a project as identified by the applicant and set forth on the certificate of public need. The timetable is used by the commissioner to evaluate the applicant's progress in completing an approved project.

"Significant change" means any alteration, modification or adjustment to a reviewable project for which a certificate of public need has been issued or requested following the public hearing which:

1. Changes the site;
2. Increases the capital expenditure amount authorized by the commissioner on the certificate of public need issued for the project by 10% or more;
3. Changes the service(s) proposed to be offered;
4. Extends the schedule for completion of the project beyond three years (36 months) from the date of certificate issuance or beyond the time period approved by the commissioner at the date of certificate issuance, whichever is greater. See 12 VAC 5-220-440 and 12 VAC 5-220-450.

"Standard review process" means the process utilized in the review of all certificate of public need requests with the exception of:

1. Certain bed relocations as specified in 12 VAC 5-220-280;
2. Certain projects that involve an increase in the number of beds in which nursing facility or extended care services are provided as specified in 12 VAC 5-220-325.

"State Medical Facilities Plan" means the planning document adopted by the Board of Health that includes, but is not limited to (i) methodologies for projecting need for medical care facility beds and services; (ii) statistical information on the availability of medical care facilities and services; and (iii) procedures, criteria and standards for review of applications for projects for medical care facilities and services. The most recent applicable State Medical Facilities Plan shall remain in force until any such chapter is amended, modified or repealed by the Board of Health.

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Part II.
General Information.

12 VAC 5-220-20. Authority for regulations.

The Virginia Medical Care Facilities Certificate of Public Need Law, which is codified as Article 1.1 (§32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia, requires the owners or sponsors of medical care facility projects to secure a certificate of public need from the State Health Commissioner prior to initiating such projects. Sections 32.1-102.2 and 32.1-12 of the Code of Virginia direct the Board of Health to promulgate and prescribe such rules and regulations as are deemed necessary to effectuate the purposes of this statute.

12 VAC 5-220-30. Purpose of chapter.

The board has promulgated this chapter to set forth an orderly administrative process for making public need decisions.

12 VAC 5-220-40. Administration of chapter.

This chapter is administered by the following:

1. The Board of Health is the governing body of the Virginia Department of Health. The Board of Health has the authority to promulgate and prescribe such rules and regulations as it deems necessary to effectuate the purposes of the Act.

2. The State Health Commissioner is the executive officer of the Virginia Department of Health. The commissioner is the designated decision maker in the process of determining public need under the Act.

12 VAC 5-220-50. Public meetings and public hearings.

All meetings and hearings convened to consider any certificate of public need application shall be open to the public in accordance with the provisions of the Virginia Freedom of Information Act (§2.1-340 et seq.) of the Code of Virginia.

12 VAC 5-220-60. Official records.

Written information including staff evaluations and reports and correspondence developed or utilized or received by the commissioner during the review of a medical care facility project shall become part of the official project record maintained by the Department of Health and shall be made available to the applicant, competing applicant and review bodies. Other persons may obtain a copy of the project record upon request. All records are subject to the Virginia Freedom of Information Act.

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12 VAC 5-220-70. Application of chapter.

This chapter has general applicability throughout the Commonwealth. The requirements of the Virginia Administrative Process Act (§9-6.14:1 et seq.) of the Code of Virginia apply to their promulgation.

12 VAC 5-220-80. Powers and procedures of chapter not exclusive.

The commissioner and the board reserve the right to authorize any procedure for the enforcement of this chapter that is not inconsistent with the provisions set forth herein and the provisions of Article 1.1 (§32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.

12 VAC 5-220-90. Annual report

The commissioner shall annually report to the Governor and the General Assembly on the status of Virginia's certificate of public need program. The report shall be issued by October 1 of each year and shall include, but need not be limited to:

1. A summary of the commissioner's actions during the previous fiscal year pursuant to Virginia's certificate of public need law;
2. A five-year schedule for analysis of all project categories which provides for the analysis of at least three project categories per year;
3. An analysis of the appropriateness of continuing the certificate of public need program for at least three project categories in accordance with the five-year schedule for analysis of all project categories;
4. An analysis of the effectiveness of the application review procedures used by the regional health planning agencies and the department required by § 32.1-102.6 of the Code of Virginia that details the review time required during the past year for various project categories, the number of contested or opposed applications and the project categories of these contested or opposed projects, the number of applications upon which the regional health planning agencies have failed to act in accordance with the timelines of § 32.1-102.6 B, and the number of deemed approvals from the department because of their failure to comply with the timelines required by § 32.1-102.6 E, and any other data determined by the commissioner to be relevant to the efficient operation of the program;
5. An analysis of health care market reform in the Commonwealth and the extent, if any, to which such reform obviates the need for the certificate of public need program;
6. An analysis of the accessibility by the indigent to care provided by medical care facilities regulated pursuant to Virginia's certificate of public need law;
7. An analysis of the relevance of Virginia's certificate of public need law to the quality of care provided by medical care facilities regulated pursuant to this law; and
8. An analysis of equipment registrations required pursuant to § 32.1-102.1:1 including type of equipment, whether an addition or replacement, and the equipment costs.

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Part III.
Mandatory Requirements.

12 VAC 5-220-100. Requirements for reviewable medical care facility projects.

Prior to initiating a reviewable medical care facility project the owner or sponsor shall obtain a certificate of public need from the commissioner. In the case of an acquisition of an existing medical care facility, the notification requirement set forth in 12VAC5-220-120 shall be met.

12 VAC 5-220-105. Requirements for registration of the replacement of existing medical equipment.

Within 30 days of any person contracting to make, or otherwise legally obligating to make, a capital expenditure for the replacement of medical equipment or otherwise acquiring replacement medical equipment for the provision of services listed in subdivision 7 of the definition of "project" in 12 VAC 5-220-10, the person shall register in writing such equipment replacement with the commissioner and the appropriate regional health planning agency. Such registration shall be made on forms provided by the department. The registration shall identify the specific unit of equipment to be replaced and the estimated capital cost of the replacement, and shall include documentation that the equipment to be replaced has previously been authorized through issuance of a certificate of public need, registered pursuant to former " 32.1-102.3:4 of the Code of Virginia or exempted pursuant to " 32.1-102.11 of the Code of Virginia.

12 VAC 5-220-110. Requirements for registration of certain capital expenditures of \$1 million or more but less than \$5 million.

At least 30 days before any person contracts to make or is otherwise legally obligated to make a capital expenditure by or on behalf of a medical care facility that is \$1 million or more but is less than \$5 million and has not been previously authorized by the commissioner, the owner of any medical care facility as defined in this chapter shall register in writing such expenditure with the commissioner. The format for registration shall include information concerning the purpose of such expenditure and projected impact that the expenditure will have upon the charges for services. For purposes of registration, the owner shall include any person making the affected capital expenditure. See definition of "project."

12 VAC 5-220-120. Requirement for notification of proposed acquisition of medical care facility.

At least 30 days before any person is contractually obligated to acquire an existing medical care facility, the cost of which is \$600,000 or more, that person shall provide written

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notification to the commissioner and the regional health planning agency that serves the area in which the facility is located. Such notification shall identify the name of the medical care facility, the current and proposed owner, the cost of the acquisition, the services to be added or deleted, the number of beds to be added or deleted, and the projected impact that the cost of the acquisition will have upon the charges of the services to be provided in the medical care facility. The commissioner shall provide written notification to the person who plans to acquire the medical care facility within 30 days of receipt of the required notification. If the commissioner finds that a reviewable clinical health service or beds are to be added as a result of the acquisition, the commissioner may require the proposed new owner to obtain a certificate prior to the acquisition. If such certificate is required, an application will be considered under an appropriate batch group which will be identified at the time of written notification by the commissioner to the applicant for such acquisition.

12 VAC 5-220-130. Significant change limitation.

No significant change in a project for which a certificate of public need has been issued shall be made without prior written approval of the commissioner. Such request for a significant change shall be made in writing by the owner to the commissioner with a copy to the appropriate regional health planning agency. The owner shall also submit the application fee to the department if applicable at the time the written request is made. The written request shall identify the nature and purpose of the change. The regional health planning agency shall review the proposed change and notify the commissioner of its recommendation with respect to the change within 30 days from receipt of the request by both the department and the regional health planning agency. Failure of the regional health planning agency to notify the commissioner within the 30-day period shall constitute a recommendation of approval. The commissioner shall act on the significant change request within 35 days of receipt. A public hearing during the review of a proposed significant change request is not required unless determined necessary by the commissioner. The commissioner shall not approve a significant change in cost for a project which exceeds the authorized capital expenditure by more than 20%. The commissioner shall not extend the schedule for completion of a project beyond three years from the date of issuance of the certificate or beyond the time period approved by the commissioner at the date of certificate issuance, whichever is greater, except when delays in completion of a project have been caused by events beyond the control of the owner and the owner has made substantial and continuing progress toward completion of the project.

12 VAC 5-220-140. Requirements for health maintenance organizations (HMO).

An HMO must obtain a certificate of public need prior to initiating a project. Such HMO must also adhere to the requirements for the acquisition of medical care facilities if appropriate. See definition of "project" and 12VAC5-220-10.

12 VAC 5-220-150. (Repealed).

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Part IV.
Determination of Public Need.
(Required Considerations).

12 VAC 5-220-160. Required considerations

In determining whether a public need exists for a proposed project, the following factors shall be taken into account when applicable:

1. The recommendation and the reasons therefor of the appropriate regional health planning agency.
2. The relationship of the project to the applicable health plans of the regional health planning agency and the Board of Health.
3. The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.
4. The need that the population served or to be served by the project has for the project, including, but not limited to, the needs of rural populations in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.
5. The extent to which the project will be accessible to all residents of the area proposed to be served and the effects on accessibility of any proposed relocation of an existing service or facility.
6. The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health planning region in which the project is proposed, in particular, the distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.
7. Less costly or more effective alternate methods of reasonably meeting identified health service needs.
8. The immediate and long-term financial feasibility of the project.
9. The relationship of the project to the existing health care system of the area in which the project is proposed; however, for projects proposed in rural areas, the relationship of the project to the existing health care services in the specific rural locality shall be considered.
10. The availability of resources for the project.
11. The organizational relationship of the project to necessary ancillary and support services.
12. The relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.
13. The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health planning region in which the project is to be located.
14. The need and the availability in the health planning region for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency

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training levels.

15. The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the commissioner may grant a certificate for a project if the commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organizations or the beds or services to be provided are not available from providers which are not health maintenance organizations or from other health maintenance organizations in a reasonable and cost effective manner.

16. The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

17. The costs and benefits of the construction associated with the proposed project.

18. The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.

19. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.

20. In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed, including, in the case of rural localities, any distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

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**Part V.
Review Process.**

12 VAC 5-220-170. Preconsultation.

Each regional health planning agency and the department shall provide upon request advice and assistance concerning community health resources needs to potential applicants. Such advice and assistance shall be advisory only and shall not be a commitment on behalf of the regional health planning agency or the commissioner.

12 VAC 5-220-180. Application forms.

A. Letter of intent. An applicant shall file a letter of intent with the commissioner to request appropriate application forms, and submit a copy of that letter to the appropriate regional health planning agency, by the later of (i) 30 days prior to the submission of an application for a project included within a particular batch group or (ii) 10 days after the first letter of intent is filed for a project within a particular batch group for the same or similar services and facilities which are proposed for the same planning district or medical service area. The letter shall identify the owner, the type of project for which an application is requested, and the proposed scope (size) and location of the proposed project. The department shall transmit application forms to the applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the department shall be considered void one year after the date of receipt of such letter. (See 12 VAC 5-220-310 C.)

B. Application fees. The department shall collect application fees for applications that request a certificate of public need. The fee required for an application shall be 1.0% of the proposed expenditure for the project, but not less than \$1,000 and no more than \$20,000.

No application will be deemed to be complete for review until the required application fee is paid. (See 12 VAC 5-220-310 C.)

C. Filing application forms. Applications must be submitted at least 40 days prior to the first day of a scheduled review cycle to be considered for review in the same cycle. All applications including the required data and information shall be prepared in triplicate; two copies to be submitted to the department; one copy to be submitted to the appropriate regional health planning agency. In order to verify the date of the department's and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document by certified mail or a delivery service, return receipt requested, or shall deliver the document by hand, with a signed receipt to be provided. No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency. (See 12 VAC 5-220-200.)

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12 VAC 5-220-190. Review for completeness.

The applicant shall be notified by the department within 15 days following receipt of the application if additional information is required to complete the application or the application is complete as submitted. No application shall be reviewed until the department has determined that it is complete. To be complete, all questions must be answered to the satisfaction of the commissioner and all requested documents supplied, when applicable and the application fee submitted. Additional information required to complete an application shall be submitted to the department and the appropriate regional health planning agency at least five days prior to the first day of a review cycle to be considered complete for review in the same review cycle. (See 12VAC5-220-200.)

12 VAC 5-220-200. One hundred ninety-day review cycle.

The department shall review the following groups of completed applications in accordance with the following 190-day scheduled review cycles and the following descriptions of projects within each group, except as provided for in 12 VAC 5-220-220.

BATCH GROUP	GENERAL DESCRIPTION	REVIEW CYCLE	
		Begins	Ends
A	General Hospitals/Obstetrical Services/ Neonatal Special Care Services	Feb. 10 Aug. 10	Aug. 18 Feb. 16
B	Open Heart Surgery/Cardiac Catheterization/ Ambulatory Surgery Centers/Operating Room Additions/Transplant Services	Mar. 10 Sep. 10	Sep. 16 Mar. 19
C	Psychiatric Facilities/Substance Abuse Treatment/Mental Retardation Facilities	Apr. 10 Oct. 10	Oct. 17 Apr. 18
D/F	Diagnostic Imaging Facilities/Services Selected therapeutic Facilities/Services	May 10 Nov. 10	Nov. 16 May 19
E	Medical Rehabilitation Beds/Services	Jun. 10 Dec. 10	Dec. 17 Jun. 18
D/F	Selected Therapeutic Facilities/Services Diagnostic Imaging Facilities/Services	Jul. 10 Jan. 10	Jan. 16 Jul. 18
G	Nursing Home Beds at Retirement Communities/ Bed Relocations/Miscellaneous	Jan. 10 Mar. 10 May 10	Jul. 18 Sep. 16 Nov. 16

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Expenditures by Nursing Homes

July 10 Jan. 16
Sep. 10 Mar. 19
Nov. 10 May 19

Batch Group A includes:

1. The establishment of a general hospital.
2. An increase in the total number of general acute care beds in an existing or authorized general hospital.
3. The relocation at the same site of 10 general hospital beds or 10% of the general hospital beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period if such relocation involves a capital expenditure of \$ 5 million or more (see 12 VAC 5-220-280).
4. The introduction into an existing medical care facility of any new neonatal special care or obstetrical services that the facility has not provided in the previous 12 months.
5. Any capital expenditure of \$5 million or more, not defined as a project category included in Batch Groups B through G, by or in behalf of a general hospital.

Batch Group B includes:

1. The establishment of a specialized center, clinic, or portion of a physician's office developed for the provision of outpatient or ambulatory surgery or cardiac catheterization services.
2. An increase in the total number of operating rooms in an existing medical care facility or establishment of operating rooms in a new facility.
3. The introduction into an existing medical care facility of any new cardiac catheterization, open heart surgery, or organ or tissue transplant services that the facility has not provided in the previous 12 months.
4. The addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization services.
5. Any capital expenditure of \$5 million or more, not defined as a project category in Batch Group A or Batch Groups C through G, by or in behalf of a specialized center, clinic, or portion of a physician's office developed for the provision of outpatient or ambulatory surgery or cardiac catheterization services.
6. Any capital expenditure of \$5 million or more, not defined as a project category in Batch Group A or Batch Groups C through G, by or in behalf of a medical care facility, that is primarily related to the provision of surgery, cardiac catheterization, open heart surgery, or organ or tissue transplant services.

Batch Group C includes:

1. The establishment of a mental hospital, psychiatric hospital, intermediate care facility

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established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facility.

2. An increase in the total number of beds in an existing or authorized mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facility.

3. An increase in the total number of mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds in an existing or authorized medical care facility which is not a dedicated mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facility.

4. The relocation at the same site of 10 mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds or 10% of the mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period if such relocation involves a capital expenditure of \$5 million or more (see 12 VAC 5-220-280).

5. The introduction into an existing medical care facility of any new psychiatric or substance abuse treatment service that the facility has not provided in the previous 12 months.

6. Any capital expenditure of \$5 million or more, not defined as a project category in Batch Groups A and B or Batch Groups D/F through G, by or in behalf of a mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facilities.

7. Any capital expenditure of \$5 million or more, not defined as a project category in Batch Groups A through B or Batch Groups D through G, by or in behalf of a medical care facility, which is primarily related to the provision of mental health, psychiatric, substance abuse treatment or rehabilitation, or mental retardation services.

Batch Group D/F includes:

1. The establishment of a specialized center, clinic, or that portion of a physician's office developed for the provision of computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging, except for the purpose of nuclear cardiac imaging.

2. The introduction into an existing medical care facility of any new computed tomography (CT), magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging services, except for the purpose of nuclear cardiac imaging that the facility has not provided in the previous 12 months.

3. The addition by an existing medical care facility of any equipment for the provision of computed tomography (CT), magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning.

4. Any capital expenditure of \$5 million or more, not defined as a project category in Batch

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Groups A, B, C, E and G, by or in behalf of a specialized center, clinic, or that portion of a physician's office developed for the provision of computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging, except that portion of a physician's office dedicated to providing nuclear cardiac imaging.

5. Any capital expenditure of \$5 million or more, not defined as a project category in Batch Groups A, B, C, E, and G, by or in behalf of a medical care facility, which is primarily related to the provision of computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging, except for the purpose of nuclear cardiac imaging.

Batch Group E includes:

1. The establishment of a medical rehabilitation hospital.
2. An increase in the total number of beds in an existing or authorized medical rehabilitation hospital.
3. An increase in the total number of medical rehabilitation beds in an existing or authorized medical care facility that is not a dedicated medical rehabilitation hospital.
4. The relocation at the same site of 10 medical rehabilitation beds or 10% of the medical rehabilitation beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period, if such relocation involves a capital expenditure of \$5 million or more (see 12 VAC 220-280).
5. The introduction into an existing medical care facility of any new medical rehabilitation service that the facility has not provided in the previous 12 months.
6. Any capital expenditure of \$5 million or more, not defined as a project category in Batch Groups A, B, C, D/F, and G, by or in behalf of a medical rehabilitation hospital.
7. Any capital expenditure of \$5 million or more, not defined as a project category in Batch Groups A, B, C, D/F, and G, by or in behalf of a medical care facility, that is primarily related to the provision of medical rehabilitation services.

Batch Group D/F includes:

1. The establishment of a specialized center, clinic, or that portion of a physician's office developed for the provision of gamma knife surgery, lithotripsy, or radiation therapy.
2. Introduction into an existing medical care facility of any new gamma knife surgery, lithotripsy, or radiation therapy services that the facility has not provided in the previous 12 months.
3. The addition by an existing medical care facility of any medical equipment for the provision of gamma knife surgery, lithotripsy, or radiation therapy.
4. Any capital expenditure of \$5 million or more, not defined as a project in Batch Groups A, B, C, E, and G, by or in behalf of a specialized center, clinic, or that portion of a physician's office developed for the provision of gamma knife surgery, lithotripsy, or radiation therapy.
5. Any capital expenditure of \$5 million or more, not defined as a project in Batch Groups

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A, B, C, E, and G, by or in behalf of a medical care facility, which is primarily related to the provision of gamma knife surgery, lithotripsy, or radiation therapy.

Batch Group G includes:

1. The establishment of a nursing home, intermediate care facility, or extended care facility of a continuing care retirement community by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.
2. The establishment of a nursing home, intermediate care facility, or extended care facility that does not involve an increase in the number of nursing home facility beds within a planning district.
3. An increase in the total number of beds in an existing or authorized nursing home, intermediate care facility, or extended care facility of a continuing care retirement community by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.
4. An increase in the total number of beds in an existing or authorized nursing home, intermediate care facility, or extended care facility that does not involve an increase in the number of nursing home facility beds within a planning district.
5. The relocation at the same site of 10 nursing home, intermediate care facility, or extended care facility beds or 10% of the nursing home, intermediate care facility, or extended care facility beds of a medical care facility, whichever is less, from one physical facility to another in any two-year period, if such relocation involves a capital expenditure of \$5 million or more (see 12 VAC 5-220-280).
6. Any capital expenditure of \$5 million or more, not defined as a project category in Batch Groups A through F, by or in behalf of a nursing home, intermediate care facility, or extended care facility, which does not increase the total number of beds of the facility.
7. Any capital expenditure of \$5 million or more, not defined as a project category in Batch Groups A through F, by or in behalf of a medical care facility, that is primarily related to the provision of nursing home, intermediate care, or extended care services, and does not increase the number of beds of the facility.

12 VAC 5-220-210. Requests for application (RFA).

The commissioner may request the submission of applications for his consideration which address a specific need for services and facilities as identified in the State Medical Facilities Plan. The department shall give notice of such RFA in a newspaper of general circulation in the locality or the planning district where the specific services or facility is requested. Such notice shall be published at least 120 days prior to the first day of the appropriate review cycle for the type of project being requested. A written copy of an RFA shall also be available upon request from the department and the regional health planning agency in the appropriate geographic area. The process for adoption of an RFA by the commissioner for projects other than nursing home bed projects (see 12VAC5-220-325) shall be set forth in the

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State Medical Facilities Plan.

12 VAC 5-220-220. Consideration of applications.

Applications for the same or similar services which are proposed for the same planning district or medical service area shall be considered as competing applications by the commissioner. The commissioner shall determine whether an application is competing and shall provide written notification to the competing applicants and the regional health planning agency. The commissioner may, upon the request of an applicant, waive the review schedule requirements of 12VAC5-220-200 in the case of a documented emergency or in cases where, as of the deadline for filing a letter of intent for the otherwise applicable cycle, there are no competing applicants, and the applicant who has filed a letter of intent for a particular project proposes to combine the intended project with another related project for which an application will be filed in a subsequent batch group.

12 VAC 5-220-230. Review of complete application.

A. Review cycle. At the close of the work day on the tenth day of the month, the department shall provide written notification to applicants specifying the acceptance date and review schedule of completed applications including the date for any informal fact-finding conference that may be held between the eightieth and ninetieth day of the review cycle. The regional health planning agency shall conduct no more than two meetings, one of which must be a public hearing conducted by the regional health planning agency board or a sub-committee of the board and provide applicants with an opportunity, prior to the vote, to respond to any comments made about the project by the regional health planning agency staff, any information in a staff report, the comments of local governing bodies in the health planning district, all other public comments, or comments by those voting in completing its review and recommendation by the sixtieth day of the cycle. By the seventieth day of the review cycle, the department shall complete its review and recommendation of an application and transmit the same to the applicant(s) and other appropriate persons. By the seventy-fifth day of the review cycle, the department shall transmit to the applicant and the appropriate other persons its determination whether an informal fact-finding conference is necessary.

An informal fact-finding conference shall be held when (i) determined necessary by the department or (ii) requested by any person seeking to be made a party to the case for] good cause. Any person seeking to be made a party to the case for] good cause shall file, no later than four days after the department has completed its review and recommendation of an application and has transmitted the same to the applicants and to persons who have prior to the issuance of the report requested a copy in writing, written notification with the commissioner, applicant(s) and other competing applicants, and regional health planning agency stating the grounds for good cause and providing the factual basis therefor under oath.

For purposes of this section, "good cause" means that (i) there is significant, relevant

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information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing or (iii) there is a substantial material mistake of fact or law in the department staff's report on the application or in the report submitted by the regional health planning agency. See § 32.1-102.6 of the Code of Virginia.

B. Time period for review. The review period shall begin on the first day of the applicable review cycle within which an application is determined to be complete, in accordance with scheduled batch review cycles described in 12 VAC 5-220-200. If the application is not determined to be complete for the applicable batch cycle within 40 calendar days from the date of submission, the application may be refiled in the next applicable batch cycle.

If the regional health planning agency has not completed its review by the sixtieth day of the review cycle, or such other period in accordance with the applicant's request for extension, and submitted its recommendation within 10 calendar days after the completion of its review, the department shall, on the eleventh day after expiration of the regional health planning agency's review period, proceed as if the regional health planning agency has recommended approval of the proposed project.

In any case in which an informal fact-finding conference is not held, the project record shall be closed on the earlier of (i) the date established for holding the informal fact-finding conference or (ii) the date that the department determines that an informal fact-finding conference is not necessary (See 12 VAC 5 220-230 A).

In any case in which an informal fact-finding conference is held, a date shall be established for closing of the record that shall not be more than 30 calendar days after the date for holding the informal fact-finding conference.

C. Determination by the Commissioner. If a determination whether a public need exists for a project is not made by the commissioner within 45 calendar days of the closing of the record, the commissioner shall notify the applicant or applicants and any persons seeking to show good cause, in writing, that the application or the applications of each shall be deemed approved 25 calendar days after the expiration of such 45 calendar day period, unless the receipt of recommendations from the person performing as hearing officer permits the commissioner to issue his case decision within that 25 calendar day period. The validity or timeliness of the aforementioned notice shall not, in any event, prevent, delay or otherwise impact the effectiveness of this section.

In any case when a determination whether a public need exists for a project is not made by the commissioner within 70 calendar days after closing of the record, the application shall be deemed approved and a certificate shall be granted.

If a determination whether a public need for a project exists is not made by the

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commissioner within 45 calendar days of the closing of the record, any person who has filed an application competing in the relevant batch review cycle or who has filed an application in response to the relevant Request for Applications issued pursuant to 12 VAC 5-220-355 may, prior to the application being deemed approved, petition for immediate injunctive relief pursuant to § 2.2-4030 of the Code of Virginia, naming as respondents the commissioner and all parties to the case. During the pendency of proceeding, no applications shall be deemed to be approved. In such a proceeding, the provisions of § 2.2-4030 of the Code of Virginia shall apply.

Deemed approvals shall be construed as the commissioner's case decision on the application pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) and shall be subject to judicial review on appeal as the commissioner's case decision in accordance with such act.

Any person who has sought to participate in the department's review of such deemed-to-be-approved application as a person showing good cause who has not received a final determination from the commissioner concerning such attempt to show good cause shall be deemed to be a person showing good cause for purposes of appeal of a deemed-to-be-approved certificate.

In any appeal of the commissioner's case decision granting a certificate of public need pursuant to a Request for Applications issued pursuant to § 32.1-102.3:2 of the Code of Virginia, the court may require the appellant to file a bond pursuant to § 8.01-676.1 of the Code of Virginia, in such sum as shall be fixed by the court for protection of all parties interested in the case decision, conditioned on the payment of all damages and costs incurred in consequence of such appeal.

The applicants, and only the applicants, shall have the authority to extend any of the time periods for review of the application, which are specified in 12 VAC 5-220-230. If all applicants consent to extending any time period in this section, the commissioner, with the concurrence of the applicants, shall establish a new schedule for the remaining time periods.

For purposes of project review, any scheduled deadlines that fall on a weekend or state holiday shall be advanced to the next work day.

D. Regional health planning agency required notifications. Upon notification of the acceptance date of a complete application as set forth in subsection A of this section of these regulations, the regional health planning agency shall provide written notification of its review schedule to the applicant. The regional health planning agency shall notify the local governing bodies in the planning district, health care providers and specifically identifiable consumer groups who may be affected by the proposed project directly by mail and shall also give notice of the public hearing in a newspaper of general circulation in such county or city wherein a project is proposed or a contiguous county or city at least nine days prior to such public hearing. Such notification by the regional health planning agency shall include: (i) the date and location

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of the public hearing which shall be conducted on the application except as otherwise provided in this chapter, in the county or city wherein a project is proposed or a contiguous county or city and (ii) the date, time and place the final recommendation of the regional health planning agency shall be made. The regional health planning agency shall maintain a verbatim record of the public hearing that includes any comments of the local governing bodies of the health planning district and all other public comments. A copy of the verbatim record shall be provided to the Department. Such public hearing record shall be maintained for at least a one year time period following the final decision on a certificate of public need application. See definition of "public hearing."

E. Ex parte contact. After commencement of a public hearing and before a final decision is made, there shall be no ex parte contacts between the State Health Commissioner and any person acting on behalf of the applicant or holder of a certificate or any person opposed to the issuance or in favor of revocation of a certificate of public need, unless written notification has been provided. See definition of "ex parte."

12 VAC 5-220-240. Participation by other persons.

Any person affected by a proposed project under review may directly submit written opinions, data and other information to the appropriate regional health planning agency and the commissioner for consideration prior to their final action.

12 VAC 5-220-250. Amendment to an application.

The applicant shall have the right to amend an application at any time. Any amendment which is made to an application following the public hearing and prior to the issuance of a certificate unless otherwise specified in this chapter shall constitute a new application and shall be subject to the review requirements set forth in Part V of this chapter. If such amendment is made subsequent to the issuance of a certificate of public need, it shall be reviewed in accordance with 12VAC5-220-130.

12 VAC 5-220-260. Withdrawal of an application.

The applicant shall have the right to withdraw an application from consideration at any time, without prejudice by written notification to the commissioner.

12 VAC 5-220-270. Action on an application.

A. Commissioner's responsibility. Decisions as to approval or disapproval of applications or a portion thereof for certificates of public need shall be rendered by the commissioner. Any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan. However, if the commissioner finds, upon presentation of appropriate evidence, that the provisions of such plan are not relevant to a

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rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable, the commissioner, consistent with such finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan.

Conditions of approval. The commissioner may condition the approval of an application for a project (i) on the agreement by the applicant to provide an acceptable level of care at a reduced rate to indigents or, (ii) on the agreement of the applicant to provide care to persons with special needs, or (iii) upon the agreement of the applicant to facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area. The terms of such agreements shall be specified in writing prior to the commissioner's decision to approve a project. Any person willfully refusing, failing or neglecting to honor such agreements shall be subject to a civil penalty of \$100 per violation per day from the date of receipt from the department of written notice of non-compliance until the date of compliance. Upon information and belief that a person has failed to honor such agreement in accordance with this provision, the department shall notify the person in writing and 15 days shall be provided for a response in writing including a plan for immediate correction. In the absence of an adequate response or necessary compliance or both, a judicial action shall be initiated in accordance with the provisions of § 32.1-27 of the Code of Virginia.

B. Notification process-extension of review time. The commissioner shall make a final determination on an application for a certificate of public need and provide written notification detailing the reasons for such determination to the applicant with a copy to the regional health planning agency within the time frames specified in 12 VAC 5-220-230 B unless authorization is given by the applicant or applicants to extend the time period. Such written notification shall also reference the factors and bases considered in making a decision on the application and, if applicable, the remedies available for appeal of such decision and the progress reporting requirements. The commissioner may approve a portion of a project provided the portion to be approved is agreed to by the applicant following consultation, which may be subject to the ex parte provision of this chapter, between the commissioner and the applicant.

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Part VI.
Expedited Review Process.

12 VAC 5-220-280. Applicability.

Projects of medical care facilities that involve relocation at the same site of 10 beds or 10% of the beds, whichever is less from one existing physical facility to another, when the cost of such relocation is less than \$ 5 million, shall be subject to an expedited review process.

12 VAC 5-220-290. Application forms.

A. Obtaining application forms. Application forms for an expedited review shall be available from the department upon the request of the applicant. The department shall transmit application forms to the applicant within seven days of receipt of such request.

B. Application fees. The department shall collect application fees for applications that request a certificate of public need under the expedited review process. No application will be reviewed until the required application fee is paid as provided in 12VAC5-220-180 B.

C. Filing application forms. All requests for a certificate of public need in accordance with the expedited review process shall be reviewed by the department and the regional health planning agency which shall each forward a recommendation to the commissioner within 40 days from the date the submitted application has been deemed complete. No application for expedited review shall be reviewed until the application form has been received by the department and the appropriate regional health planning agency, has been deemed complete, and the application fee has been paid to the department.

12 VAC 5-220-300. Participation by other persons.

Any person directly affected by the review of a project under the expedited review process may submit written opinions, data and other information to the appropriate regional health planning agency and to the commissioner prior to their final action.

12 VAC 5-220-310. Action on applications.

A. Decisions to approve any project under the expedited review process shall be rendered by the commissioner within 45 days of the receipt of such completed request. The commissioner shall approve and issue a certificate for any project which is determined to meet the criteria for expedited review set forth in 12 VAC 5-220-280.

B. If the commissioner determines that a project does not meet the criteria for an expedited review set forth in 12 VAC 5-220-280, the applicant will be notified in writing of such determination within 45 days of the receipt of such request. In such cases, the department will forward the appropriate forms to the project applicant for use in filing an application for review

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of a project in the appropriate review cycle in accordance with Part V of this chapter.

C. Any project which does not qualify for an expedited review in accordance with 12 VAC 5-220-280, as determined by the commissioner, shall be exempted from the requirements of 12 VAC 5-220-280 A and B when such project is filed for consideration in accordance with Part V of this chapter.

12VAC5-220-320. [Repealed]

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Part VII.
New Nursing Home Bed Review Process.

12 VAC 5-220-325. Applicability.

The following categories of projects as determined by the State Health Commissioner shall be subject to the nursing home bed review process when they involve an increase in the number of nursing home facility beds in Virginia. (For Continuing Care Retirement Community nursing home beds, see Part V (12VAC5-220-170 et seq.) of this chapter.)

1. The establishment of a nursing home, intermediate care facility, or extended care facility, except when such nursing home, intermediate care facility, or extended care facility is proposed by a continuing care retirement community and the project is sponsored by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.

2. An increase in the total number of beds in an existing or authorized nursing home, intermediate care facility, or extended care facility, except when the nursing home, intermediate care facility, or extended care facility is a component of a continuing care retirement community and the project is sponsored by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.

3. An increase in the total number of nursing home beds, intermediate care facility beds, or extended care facility beds in an existing or authorized medical care facility which is not a dedicated nursing home, intermediate care facility, or extended care facility.

4. The introduction into any existing medical care facility of any new nursing home service such as intermediate care facility services, extended care facility services or skilled nursing facility services except when such medical care facility is an existing nursing home as defined in §32.1-123 of the Code of Virginia.

12VAC5-220-330. [Repealed]

12 VAC 5-220-335. Request for Applications (RFA).

A. Frequency. The commissioner shall periodically issue, in consultation and cooperation with the Department of Medical Assistance Services, a Request for Applications (RFA) from project applicants proposing projects which would result in an increase in the number of beds in which nursing facility or extended care services are provided. An RFA shall be issued at least annually. (See 12VAC5-220-325)

B. Issuance. At least 60 days prior to the issuance of a RFA, the board shall publish the proposed RFA in the Virginia Register for public comment together with an explanation of (i) the regulatory basis for the planning district bed needs set forth in the proposed RFA and (ii) the rationale for the RFA's planning district designations. Any person objecting to the contents of the proposed RFA may notify, within 14 days of the publication, the board and the commissioner of his objection and the objection's regulatory basis. The commissioner shall prepare, and deliver by registered mail, a written response to each such objection within two weeks of the date of receiving the objection. The objector may file a rebuttal to the commissioner's response in

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writing within five days of receiving the commissioner's response. If objections are received, the board shall, after considering the provisions of the RFA, any objections, the commissioner's responses, and if filed, any written rebuttals of the commissioner's responses, hold a public hearing to receive comments on the specific RFA. Prior to making a decision on the RFA, the commissioner shall consider any recommendations made by the board.

C. Content. A RFA from project applicants proposing projects which would result in an increase in the number of beds in which nursing facility or extended care services are provided shall be based on analyses of the need for increases in the nursing home bed supply in each of Virginia's planning districts in accordance with standards included in the State Medical Facilities Plan. Such RFAs shall also include a schedule for the review of applications submitted in response to the RFA which allows for at least 120 days between the day on which the RFA is issued and the first day of the review cycle for such applications.

12VAC5-220-340. [Repealed]

12 VAC 5-220-345. Limitation on acceptance of nursing home bed applications.

Applications for projects which would result in an increase in the number of beds in which nursing facility or extended care services are provided (see 12VAC5-22-325) shall only be accepted for review when properly filed in response to a RFA. Furthermore, the commissioner shall only accept for review applications which propose projects located in the planning districts from which applications are requested in the RFA and propose authorization of a number of new beds in which nursing facility or extended care services are provided which is less than or equal to the total number of beds identified as needed for the planning district in which the project will be located.

12VAC5-220-350. [Repealed]

12 VAC 5-220-355. Application forms.

A. Letter of intent. A nursing home bed applicant shall file a letter of intent with the commissioner to request appropriate application forms, and submit a copy of that letter to the appropriate regional health planning agency by the letter of intent deadline specified in the RFA. The letter shall identify the owner, the type of project for which an application is requested, and the proposed scope (size) and location of the proposed project. The department shall transmit application forms to the applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the department shall be considered void if an application is not filed for the project by the application deadline specified in the RFA.

B. Application fees. The department shall collect application fees for applications that request a nursing home bed certificate of public need. The fee required for an application is 1.0% of the proposed capital expenditure for the project but no less than \$1,000 and no more than \$20,000. No application will be deemed to be complete for review until the required

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application fee is paid.

C. Filing application forms. Applications must be submitted to the department and the appropriate regional health planning agency by the application filing deadline specified in the RFA. All applications including the required data and information shall be prepared in triplicate; two copies to be submitted to the department; one copy to be submitted to the appropriate regional health planning agency. In order to verify the department and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document by certified mail or a delivery service, return receipt requested, or shall deliver the document by hand, with the signed receipt to be provided. No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency.

12VAC5-220-360. [Repealed]

12 VAC 5-220-365. Review for completeness.

The applicant shall be notified by the department within 15 days following receipt of the application if additional information is required to complete the application or the application is complete as submitted. No application shall be reviewed until the department has determined that it is complete. To be complete, all questions and information items requested on the application must be completely addressed and the application fee submitted. Additional information required to complete an application shall be submitted to the department and the appropriate regional health planning agency at least five days prior to the first day of the review cycle, as specified in the RFA, to be considered in the review cycle.

12VAC5-220-370. [Repealed]

12 VAC 5-220-375. Consideration of applications.

Nursing home bed applications proposed for the same planning district shall be considered as competing applications by the commissioner. The commissioner shall determine whether an application is competing and provide written notification to the competing applicants and the regional health planning agency.

12VAC5-220-380. [Repealed]

12 VAC 5-220-385. Review of complete application.

A. Review Cycle. The department shall provide written notification to applicants specifying the acceptance date and review schedule of completed applications including the date for any informal fact-finding conference that may be held between the eightieth and ninetieth day of the review cycle. The regional health planning agency shall conduct no more than two meetings, one of which must be a public hearing conducted by the regional health planning agency board

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or a sub-committee of the board and provide applicants with an opportunity, prior to the vote, to respond to any comments made about the project by the regional health planning agency staff, any information in a staff report, the comments of the local governing bodies in the health planning district, all other public comments, or comments by those voting in completing its review and recommendation by the sixtieth day of the cycle. By the seventieth day of the review cycle, the department shall complete its review and recommendation of an application and transmit the same to the applicant or applicants and other appropriate persons. By the seventy-fifth day of the review cycle, the department shall transmit to the applicants and other appropriate persons, its determination whether an informal fact-finding conference is necessary.

An informal fact-finding conference shall be held when (i) determined necessary by the department or (ii) requested by any person seeking to demonstrate good cause. Any person seeking to demonstrate good cause shall file, no later than four days after the department has completed its review and recommendation of an application and has transmitted the same to the applicants and to persons who have prior to the issuance of the report requested a copy in writing, written notification with the commissioner, applicant or applicants and other competing applicants, and regional health planning agency stating the grounds for good cause and providing the factual basis therefor under oath.

For purposes of this section, "good cause" means that (i) there is significant, relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing or (iii) there is a substantial material mistake of fact or law in the department staff's report on the application or in the report submitted by the regional health planning agency. (See § 32.1-102.6 of the Code of Virginia.)

B. Time period for review. The review period shall begin on the first day of the applicable review cycle within which an application is determined to be complete, in accordance with scheduled batch review cycles described in 12 VAC 5-220-200. If the application is not determined to be complete for the applicable batch cycle within 40 calendar days from the date of submission, the application may be refiled in the next applicable batch cycle.

If the regional health planning agency has not completed its review by the sixtieth day of the review cycle, or such other period in accordance with the applicant's request for extension, and submitted its recommendation within 10 calendar days after the completion of its review, the department shall, on the eleventh day after expiration of the regional health planning agency's review period, proceed as if the regional health planning agency has recommended approval of the proposed project.

In any case in which an informal fact-finding conference is not held, the project record shall be closed on the earlier of (i) the date established for holding the informal fact-finding conference or (ii) the date that the department determines that an informal fact-finding conference is not necessary (See 12 VAC 5 220-230 A).

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In any case in which an informal fact-finding conference is held, a date shall be established for closing of the record which shall not be more than 30 calendar days after the date for holding the informal fact-finding conference.

C. Determination by the Commissioner. If a determination whether a public need exists for a project is not made by the commissioner within 45 calendar days of the closing of the record, the commissioner shall notify the applicant or applicants and any person seeking to show good cause, in writing, that the application or the applications of each shall be deemed approved 25 calendar days after the expiration of such 45-calendar-day period, unless the receipt of recommendations from the person performing the hearing officer functions permits the commissioner to issue his case decision within that 25-calendar-day period. The validity or timeliness of the aforementioned notice shall not, in any event, prevent, delay or otherwise impact the effectiveness of this section.

In any case when a determination whether a public need exists for a project is not made by the commissioner within 70 calendar days after closing of the record, the application shall be deemed approved and a certificate shall be granted.

If a determination whether a public need for a project exists is not made by the commissioner within 45 calendar days of the closing of the record, any applicant who is competing in the relevant batch review cycle or who has filed an application in response to the relevant Request for Applications issued pursuant to 12 VAC 5-220-355 may, prior to the application being deemed approved petition for immediate injunctive relief pursuant to § 2.2-4030 of the Code of Virginia, naming as respondents the commissioner and all parties to the case. During the pendency of proceeding, no applications shall be deemed to be approved. In such a proceeding, the provisions of § 2.2-4030 of the Code of Virginia shall apply.

Deemed approvals shall be construed as the commissioner's case decision on the application pursuant to the Administrative Process Act (§ 2.2-4000 et seq.) and shall be subject to judicial review on appeal as the commissioner's case decision in accordance with such act.

Any person who has sought to participate in the department's review of such deemed-to-be-approved application as a person showing good cause who has not received a final determination from the commissioner concerning such attempt to show good cause petition prior to the date on which the application was approved, shall be deemed to be a person showing good cause for purposes of appeal of a deemed-to-be-approved certificate.

In any appeal of the commissioner's case decision granting a certificate of public need pursuant to a Request for Applications issued pursuant to § 32.1-102.3:2 of the Code of Virginia, the court may require the appellant to file a bond pursuant to § 8.01-676.1 of the Code of Virginia, in such sum as shall be fixed by the court for protection of all parties interested in the case decision, conditioned on the payment of all damages and costs incurred in consequence of

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such appeal.

The applicants, and only the applicants, shall have the authority to extend any of the time periods for review of the application, which are specified in 12 VAC 5-220-230 . If all applicants consent to extending any time period in this section, the commissioner, with the concurrence of the applicants, shall establish a new schedule for the remaining time periods.

D. Regional health planning agency required notifications. Upon notification of the acceptance date of a complete application as set forth in subsection A of this section, the regional health planning agency shall provide written notification of its review schedule to the applicant. The regional health planning agency shall notify the local governing bodies in the planning district, health care providers and specifically identifiable consumer groups who may be affected by the proposed project directly by mail and shall also give notice of the public hearing in a newspaper of general circulation in such county or city wherein a project is proposed or a contiguous county or city at least nine days prior to such public hearing. Such notification by the regional health planning agency shall include: (i) the date and location of the public hearing which shall be conducted on the application except as otherwise provided in this chapter, in the county or city wherein a project is proposed or a contiguous county or city and (ii) the date, time and place the final recommendation of the regional health planning agency shall be made. The regional health planning agency shall maintain a verbatim record of the public hearing that includes any comments of the local governing bodies of the health planning district and all other public comments. A copy of the verbatim record shall be provided to the Department. Such public hearing record shall be maintained for at least a one year time period following the final decision on a certificate of public need application. See definition of "public hearing."

E. Ex parte contact. After commencement of a public hearing and before a final decision is made, there shall be no ex parte contacts between the State Health Commissioner and any person acting on behalf of the applicant or holder of a certificate or any person opposed to the issuance or in favor of revocation of a certificate of public need, unless written notification has been provided. See definition of "ex parte."

12VAC5-220-390. [Repealed]

12 VAC 5-220-395. Participation by other persons.

Any person affected by a proposed project under review may directly submit written opinions, data and other information to the appropriate regional health planning agency and the commissioner for consideration prior to their final action.

12VAC5-220-400. [Repealed]

12 VAC 5-220-405. Amendment to an application.

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The applicant shall have the right to amend an application at any time. Any amendment which is made to an application following the public hearing and prior to the issuance of a certificate unless otherwise specified in this chapter shall constitute a new application and shall be subject to the review requirements set forth in this part of this chapter. If such amendment is made subsequent to the issuance of a certificate of public need, it shall be reviewed in accordance with 12VAC5-220-130.

12 VAC 5-220-410. Withdrawal of an application.

The applicant shall have the right to withdraw an application from consideration at any time without prejudice by written notification to the commissioner.

12 VAC 5-220-420. Action on an application.

A. Commissioner's responsibility. Decisions as to approval or disapproval of applications or a portion thereof for certificates of public need shall be rendered by the commissioner. Any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan. However, if the commissioner finds, upon presentation of appropriate evidence, that the provisions of such plan are not relevant to a rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable, the commissioner, consistent with such finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan.

The commissioner may condition the approval of an application for a project (i) on the agreement by the applicant to provide an acceptable level of care at a reduced rate to indigents or, (ii) on the agreement of the applicant to provide care to persons with special needs, or (iii) upon the agreement of the applicant to facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area. The terms of such agreements shall be specified in writing prior to the commissioner's decision to approve a project. Any person willfully refusing, failing or neglecting to honor such agreements shall be subject to a civil penalty of \$100 per violation per day from the date of receipt from the department of written notice of noncompliance until the date of compliance. Upon information and belief that a person has failed to honor such agreement in accordance with this provision, the department shall notify the person in writing and 15 days shall be provided for a response in writing including a plan for immediate correction. In the absence of an adequate response or necessary compliance or both, a judicial action shall be initiated in accordance with the provisions of § 32.1-27 of the Code of Virginia.

B. Notification process-extension of review time. The commissioner shall make a final determination on an application for a certificate of public need and provide written notification detailing the reasons for such determination to the applicant with a copy to the regional health planning agency within the time frames specified in 12 VAC 5-220-385 B unless an authorization is given by the applicant(s) to extend the time period. Such written notification

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shall also reference the factors and bases considered in making a decision on the application and, if applicable, the remedies available for appeal of such decision and the progress reporting requirements. The commissioner may approve a portion of a project provided the portion to be approved is agreed to by the applicant following consultation, which may be subject to the ex parte provision of this chapter, between the commissioner and the applicant.

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Part VIII.

Duration, Extension, Revocation of Certificates.

12 VAC 5-220-430. Duration.

A certificate of public need shall be valid for a period of 12 months and shall not be transferrable from the certificate holder to any other legal entity regardless of the relationship, under any circumstances.

12 VAC 5-220-440. Extension.

A certificate of public need is valid for a 12-month period and may be extended by the commissioner for additional time periods which shall be specified at the time of the extension.

A. Basis for certificate extension within 24 months. An extension of a certificate of public need beyond the expiration date may be granted by the commissioner by submission of evidence to demonstrate that progress is being made towards the completion of the authorized project as defined in 12VAC5-220-450. Such request shall be submitted to the commissioner in writing with a copy to the appropriate regional health planning agency at least 30 days prior to the expiration date of the certificate or period of extension.

B. Basis for certificate extension beyond 24 months. An extension of a certificate of public need beyond the two years following the date of issuance may be granted by the commissioner when substantial and continuing progress is being made towards the development of the authorized project. In making the determination, the commissioner shall consider whether: (i) any delays in development of the project have been caused by events beyond the control of the owner; (ii) substantial delays in development of the project may not be attributed to the owner; and (iii) a schedule of completion has been provided and determined to be reasonable. Such request shall be submitted in writing with a copy to the appropriate regional health planning agency at least 30 days prior to the expiration date of the certificate or period of extension. The commissioner shall not grant an extension to the schedule for completion of a project beyond three years (36 months) of the date of certificate issuance or beyond the time period approved at the date of certificate issuance, whichever is greater, unless such extension is authorized in accordance with the provisions for a significant change. See 12VAC5-220-130, Significant change limitation.

C. Basis for indefinite extension. A certificate shall be considered for an indefinite extension by the commissioner when satisfactory completion of a project has been demonstrated as set forth in subsection C of 12VAC5-220-450.

D. Regional health planning agency review. All requests for an extension of a certificate of public need shall be reviewed by the appropriate regional health planning agency within 30 days of receipt by the department and the regional health planning agency. The recommendations on the request by that agency shall be forwarded to the commissioner who shall act upon the

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progress report within 35 days of receipt by the department and the regional health planning agency. Failure of the regional health planning agency to notify the commissioner within the time frame prescribed shall constitute a recommendation of approval by such regional health planning agency.

E. Notification of decision. Extension of a certificate of public need by the commissioner shall be made in the form of a letter from the commissioner with a copy to the appropriate regional health planning agency and shall become part of the official project file.

12 VAC 5-220-450. Demonstration of progress.

The applicant shall provide reports to demonstrate progress made towards the implementation of an authorized project in accordance with the schedule of development which shall be included in the application. Such progress reports shall be filed in accordance with the following intervals and contain such evidence as prescribed at each interval:

A. Twelve months following issuance. Documentation that shows: (i) proof of ownership or control of site; (ii) the site meets all zoning and land use requirements; (iii) architectural planning has been initiated; (iv) preliminary architectural drawings and working drawings have been submitted to appropriate state reviewing agencies and the State Fire Marshal; (v) construction financing has been completed or will be completed within two months and (vi) purchase orders or lease agreements exist for equipment and new service projects.

B. Twenty-four months following issuance. Documentation that shows that (i) all required financing is completed; (ii) preconstruction site work has been initiated; (iii) construction bids have been advertised and the construction contractor has been selected; (iv) the construction contract has been awarded and (v) construction has been initiated.

C. Upon completion of a project. Any documentation not previously provided which: (i) shows the final costs of the project, including the method(s) of financing; and (ii) shows that the project has been completed as proposed in accordance with the application originally submitted, including any subsequent approved changes. See "completion" as defined in 12VAC5-220-10.

12 VAC 5-220-460. Revocation of certificate.

A. Lack of progress. Failure of any project to meet the progress requirements stated in 12VAC5-220-450 shall be cause for certificate revocation, unless the commissioner determines sufficient justification exists to permit variance, considering factors enumerated in 12VAC5-220-450.

B. Failure to report progress. Failure of an applicant to file progress reports on an approved project in accordance with 12VAC5-220-450 shall be cause for revocation, unless, due to extenuating circumstances, the commissioner, in his sole discretion, extends the certificate, in accordance with subsection B of 12VAC5-220-440.

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C. Unapproved changes. Exceeding a capital expenditure amount not authorized by the commissioner or not consistent with the schedule of completion shall be cause for revocation. See definition of "significant change" and "schedule of completion."

D. Failure to initiate construction. Failure to initiate construction of the project within two years following the date of issuance of the certificate of public need shall be cause for revocation, unless due to extenuating circumstances the commissioner extends the certificate, in accordance with subsection B of 12VAC5-220-440.

E. Misrepresentation. Upon determination that an applicant has knowingly misrepresented or knowingly withheld relevant data or information prior to issuance of a certificate of public need, the commissioner may revoke said certificate.

F. Noncompliance with assurances. Failure to comply with the assurances or intentions set forth in the application or written assurances provided at the time of issuance of a certificate of public need shall be cause for revocation.

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**Part IX.
Appeals.**

12 VAC 5-220-470. Judicial review.

Appeals to a circuit court shall be governed by the Virginia Administrative Process Act, §§2.2-4000 et seq. of the Code of Virginia and Part Two A of the Rules of the Supreme Court of Virginia.

**Part X.
Sanctions.**

12VAC5-220-480. Violation of rules and regulations.

Commencing any project without a certificate required by this chapter shall constitute grounds for refusing to issue a license for such project.

12VAC5-220-490. Injunctive relief.

On petition of the commissioner, the Board of Health or the Attorney General, the circuit court of the county or city where a project is under construction or is intended to be constructed, located or undertaken shall have jurisdiction to enjoin any project which is constructed, undertaken or commenced without a certificate or to enjoin the admission of patients to the project or to enjoin the provision of services through the project.

**Part XI.
Other.**

12VAC5-220-500. Exemption of Virginia Veterans Care Center.

Notwithstanding the foregoing and other provisions of Article 1.1 (§32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia, the Virginia Veterans Care Center authorized by Chapter 668, 1989 Acts of Assembly, shall be exempt from all certificate of public need review requirements as a medical care facility.

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FORMS

Application for Expedited Review for Certificate of Public Need (eff. 6/94).

Registration Form for Capital Expenditures of \$1,000,000 or More But Less than \$2,000,000 Which are Not Defined as a Project on or After July 1, 1993.

Request for Extension of a Certificate of Public Need Beyond Two Years from Date of Issuance.

Request for Extension of a Certificate of Public Need Beyond One Year, But Less than Two Years from Date of Issuance (Rev. 7/26/93).

Application for a Medical Care Facilities Certificate of Public Need - Outpatient Facilities (Rev. 12/10/92).

Application for a Medical Care Facilities Certificate of Public Need - Hospitals (Rev. 12/10/92).

Application for a Medical Care Facilities Certificate of Public Need - Long-Term Care Facilities (Rev. 12/10/92).